UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation *This Document Relates to All Actions*	Case No. 19-md-02875 (RBK/KW)

PLAINTIFFS' SECOND SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS TO RETAIL PHARMACY DEFENDANTS RELATING TO LOSARTAN AND IRBESARTAN

TO ALL PHARMACY DEFENDANTS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 34 and Local Civil Rule 34.1, Plaintiffs propound the following requests upon each Retail Pharmacy Defendant.[1] These requests are without prejudice to Plaintiffs' rights to serve other requests consistent with Rules 26 and 34.

The requests that follow track the Court-Approved Requests for Production to be answered by the Retail Pharmacy Defendants for Losartan and Irbesartan.[2] The Retail Pharmacy Defendants have previously advised, and Plaintiffs understand, that there remain differences in the ability of

[1] To the extent it applies these requests are made in accordance with the Court's rulings at oral argument on December 11, 2019 and December 18, 2019, and in the Order filed on December 13, 2019, as well as the Court's Orders on macro discovery issues filed on November 25, 2019.
[2] To the extent it applies, each request is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues; the November 25, 2019 Order on macro discovery issues pertaining to the Manufacturing Defendants (Dkt. 303); the parties' representations as reflected in the record of the December 11, 2019 discovery hearing; and the Court's oral and/or written rulings following the December 11, 2019 discovery hearing, the January 15, 2020 discovery hearing, the January 28, 2020 discovery conference, the February 13, 2020 discovery conference, and the July 6, 2020 macro discovery hearing.

each Retail Pharmacy Defendant to respond to the requests below, including differences in what data is available, and in the type and extent of data that is available in a reasonably accessible format. Following service of these requests for production, each Retail Pharmacy Defendant shall serve its own individual responses to the requests set forth below, including identification of any specific issues that the Retail Pharmacy Defendant has with the requests. The parties will meet and confer in good faith on the substance of any such responses, to the extent necessary, and to address any deficiencies or Plaintiffs' reasonable questions regarding Retail Pharmacy Defendants' responses.

DEFINITIONS

"Active Pharmaceutical Ingredient" ("API") is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance. 21 C.F.R. § 207.1; see also 21 C.F.R. § 314.3.

"API Manufacturer" is defined as any entity identified as a Defendant in Plaintiffs' Master Complaints that manufactures the active pharmaceutical ingredient (API) for losartan and/or irbesartan.

"Finished Dose Manufacturer" includes any entity identified as a Defendant in Plaintiffs' Master Complaints that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of losartan and/or irbesartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

"Manufacturer Defendants" includes API Manufacturers and Finished Dose Manufacturers including any subsidiaries or affiliated entities.

"Communication(s)" means the transmittal of information, in the form of facts, ideas, inquiries, documents or otherwise, and includes all transmissions of information received or transmitted by you, including correspondence, regardless of whether you are an author or addressee of such transmittal.

"Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof.

This definition includes drafts, and copies or duplicates of documents contemporaneously or subsequently created inclusive of any that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form). Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database. For purposes of these discovery requests,

"Documents" shall refer only to centrally stored, non- custodial data maintained by the retailer pharmacy in the ordinary course of business and available via reasonable search of available records and in a reasonably accessible format, and shall not refer to documents or data maintained solely by individual stores or pharmacies, or to emails or custodial data held by individual employees of the Retail Pharmacy Defendants.

Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is January 1, 2011 through December 31, 2019.

"Retail Pharmacy Defendants" refers to any and all entities listed by name as "Retail Pharmacy Defendants" in Plaintiffs' Master Complaints, including any agents or predecessor entities.

"TPP" refers to Third Party Payors, including health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payors, and any other health benefit provider in the United States of America and its territories.

"Losartan" or "LCDs" means any drug with losartan as an active ingredient. For purposes of these Requests, "Losartan" or "LCDs" is limited to only those drugs with a National Drug Code (NDC) associated with any of the Manufacturer Defendants identified in Plaintiffs' Master Complaints.

"Irbesartan" or "ICDs" means any drug with irbesartan as an active ingredient. For purposes of these Requests, "Irbesartan" or "ICDs" is limited to only those drugs with a National Drug Code (NDC) associated with any of the Manufacturer Defendants identified in Plaintiffs' Master Complaints.

"Recalled Product" means any drug with losartan or irbesartan as an active ingredient, as well as all finished drug formulations of losartan or irbesartan, including any losartan-containing drug or irbesartan-containing drug, that was subject to a voluntary or mandatory recall, to the extent identifiable from Documents kept by the Retail Pharmacy Defendant(s) in the ordinary course of business.

"You," "your" or **"defendant"** shall be used interchangeably and refers to the parties to which these requests are directed.

"Drug Supply Chain Security Act" refers to Pub. L. 113-54 and regulations promulgated thereunder.

"Wholesaler Defendants" refers to Amerisource Bergen Corporation, Cardinal Health, Inc., or McKesson Corporation, as identified in Plaintiffs' Master Complaints, including any agents, employees, or predecessor entities, to the extent known to the Retail Pharmacy Defendants.

INSTRUCTIONS

Non-privileged information: These Requests seek only information that is not privileged or otherwise protected from disclosure by applicable protection, including but not limited to work product protection or other requirements imposed or protections afforded by applicable law or regulation. This does not relieve any responding Defendant from serving a privilege log consistent with the Federal Rules of Civil Procedure.

REQUESTS FOR THE PRODUCTION OF DOCUMENTS

REQUEST NO. 1: All documents and communications regarding the process for sourcing of LCDs and/or ICDs and the manufacturers who made them that were purchased by you during the relevant time period, including any policies, due diligence, site visits, supplier questionnaires, and inspection documents.

REQUEST NO. 2: All documents and communications with your generic drug suppliers at all levels of the supply chain, regarding the location and/or identity of the manufacturer of the API of the generic drug products you sell, including but not limited to the LCDs and/or ICDs.

REQUEST NO. 3: All documents and communications regarding the standard supply/distribution agreements between you and any Manufacturer or other Defendant regarding LCDs and/or ICDs, including any agreement related to the quality of the LCDs and/or ICDs, purity of the LCDs and/or ICDs, manufacture of the LCDs and/or ICDs, or potential contamination of the LCDs and/or ICDs.

REQUEST NO. 4: All documents and communications regarding the Drug Supply Chain Security Act, and what your obligations are to be in compliance with that Act, and generic drug sourcing decisions and whether those decisions may impact your compliance with the Drug Supply Chain Security Act.

REQUEST NO. 5: All documents and communications between you and any Manufacturer Defendant, regarding the purchase or supply of LCDs and/or ICDs during the relevant time period.

REQUEST NO. 6: All documents and communications provided or directed to consumers and TPPs, related to the transactional purchase or dispensing of LCDs and/or ICDs.

REQUEST NO. 7: All documents and communications with any Manufacturer Defendant, Retail Pharmacy Defendant, Wholesaler, Repackager, or Relabeler Defendant or regulatory authority (including but not limited to the FDA), relating to the contamination of LCDs and/or ICDs with nitrosamines.

REQUEST NO 8: All documents and communications with any consumer or third-party payor, relating to the contamination of LCDs and/or ICDs with nitrosamines.

REQUEST NO. 9: All documents and communications regarding changes to the sourcing of generic drug products as a result of the nitrosamine contamination of the LCDs and/or ICDs.

REQUEST NO. 10: All documents and communications regarding the recall of the LCDs and/or ICDs, including but not limited to those related to the retention, sequestration, return or destruction of the LCDs and/or ICDs.

REQUEST NO. 11: All documents and communications related to either seeking refunds or credits for any LCDs and/or ICDs contaminated with nitrosamines, or issuing any refunds or

credits related to LCDs and/or ICDs contaminated with nitrosamines.

REQUEST NO 12: All documents and communications related to LCD and/or ICD testing and testing results of LCDs and/or ICDs provided to you, prepared by or for you, or otherwise available to you.

REQUEST NO. 13: All documents and communications that can or may identify potential purchasers of LCDs and/or ICDs as well as their addresses (mail and email) and other potential sources of identifying information, including loyalty reward data, phone numbers, and other sources of data not previously searched through and/or reviewed previously.

Dated: June 2, 2023

/s/ Adam M. Slater
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CERTIFICATE OF SERVICE

I certify that on the 2nd[nd] day of June 2023, I electronically transmitted the attached document to counsel of record in the above-captioned case.

/s/ Marlene J. Goldenberg
Marlene J. Goldenberg